



SEP 23 1999

1401 Rockville Pike  
Rockville MD 20852-1448

Our Reference Number: 98-1078  
Label Review Number: 19980929001

Roberta L. McKee, Ph.D.  
Merck & Co., Inc.  
P.O. Box 4  
Sumneytown Pike  
West Point, PA 19486

Dear Dr. McKee:

The Labeling Supplement to your License Application for Hepatitis B (Recombinant) Vaccine, to include the addition of two doses of the 10 mcg formulation (1.0 mL) administered at 0 and 4 to 6 months as an alternate regimen for the routine vaccination of healthy adolescents 11 to 15 years of **age**, has been approved. This information will be included in your License Application file.

Please submit three copies of final printed labeling, under label review number 19980929001, at the time of use and include part II of the label transmittal form with completed implementation information.

Sincerely yours,

A handwritten signature in cursive script, reading "P. Patriarca", is written above the typed name.

Peter A. Patriarca, M.D.  
Director  
Division of Viral Products  
Office of Vaccines  
Research and Review  
Center for **Biologics**  
Evaluation and Research